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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,556	09/24/1999	Gertrud Hotten	100564-09021	3191

6449 7590 04/15/2004

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WASHINGTON, DC 20005

EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/901,556

**Applicant(s)**

HOTTEN ET AL.

**Examiner**

Prema M Mertz

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-35 is/are pending in the application.
- 4a) Of the above claim(s) 24-29, 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-23, 30, 33-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Claims 20-35 are pending in the instant application. Claims 24-29, 31-32 are withdrawn from consideration. Claims 21, 23, amended claims 20, 22, 30 (2/13/2004), and new claims 33-35 (2/13/2004) are under consideration.

2. Receipt of applicant's arguments filed on 2/13/2004 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 2/13/2004:

- (i) the objection to the title of the invention;
- (ii) the objection to the specification for lack of a proper content of the abstract; and
- (iii) the rejection of claims 20-21, 30, under 35 U.S.C. 112, first paragraph, as lacking enablement for the mature protein encoded by the nucleotide sequence of SEQ ID NO:1.

4. Applicants arguments filed on 2/13/2004 have been fully considered but were persuasive in part. The issues remaining and new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112, first paragraph***

6. Claims 20-23, 30, are rejected under 35 U.S.C. 112, first paragraph, as containing an adequate written description.

This rejection is maintained for reasons of record set forth at pages 3-5 of the previous Office action of 10/15/2003.

Applicant argues that these claims have been amended to clarify that the antibodies bind to a part of the recited protein. However, contrary to Applicants arguments, claim 20 (on line 3)

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and claim 30 (on line 7) still recite “comprising” which encompasses in addition to the amino acid sequence of the desired protein, other additional amino acid sequences and the instant specification does not provide an adequate description of the genus of antibody compounds encompassed by these claims. In view of the limitation “comprising”, claims 20-23 and 30 are rejected under 35 U.S.C. 112, first paragraph, as lacking an adequate written description.

7. Claims 20-23, 30, are rejected under 35 U.S.C. 112, first paragraph, as lacking enablement.

This rejection is maintained for reasons of record set forth at pages 6-8 of the previous Office action of 10/15/2003.

Applicants argue that the amendments to the claims clarify that additional amino acids may be included in the protein but the antibody binds to the part of the protein defined in the claims and the antibody does not bind to a “FLAG epitope, polyhistidine tail or Protein A fragment”. However, contrary to Applicants arguments, the recitation of “comprising” in claim 20 (on line 3) and claim 30 (on line 7), encompasses an antibody, which binds to an epitope that is not contained within SEQ ID NO:3. The instant specification, does not provide the guidance needed to produce an antibody which binds to any epitope other than an epitope which is contained within SEQ ID NO:3 of the instant application.

***Claim rejections-35 USC § 112, second paragraph***

8. Claims 20-23, 30, 33-35 are rejected under 35 U.S.C. § 112, second paragraph.

This rejection is maintained for reasons of record set forth at pages 8-9 of the previous Office action of 10/15/2003.

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With respect to claims 23 and 30, Applicants argue that the language “essentially the same... activities” was not found indefinite in the parent application. However, contrary to applicants arguments, each application is examined on its own merits and therefore, this rejection is being maintained for reasons of record.

With respect to claim 22, line 3, which recites the new limitation “has”, this limitation is also considered open language. It is suggested that the claim be amended to recite “consisting of”.

With respect to claim 33, line 2, which recites “binds to a part of said protein which is a fragment of SEQ ID NO:3”, the language is redundant. It is suggested that the claim be amended to recite “binds to a fragment of SEQ ID NO:3”.

Claim 34 recites the limitation "the same amino acid sequence" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Similarly with respect to claim 35, lines 5 and 11, the recitation of “part” is unclear. It is suggested that the claim be amended to recite “fragment”.

***Claim Rejections - 35 USC § 102***

9. Claims 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by the Hopp et al. patent (5,011,912).

This rejection is maintained for reasons of record set forth at page 9 of the previous Office action of 10/15/2003.

Applicants argue that the sequence disclosed in Hopp is not included in SEQ ID NO:3 or encoded by SEQ ID NO:1 and therefore Hopp does not anticipate the present claims. However, contrary to Applicants arguments, Hopp still describes the invention now claimed, and anticipates the instant claims because the claims recite, “comprising” which claims encompass

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an antibody to any hapten or tag, including the flag epitope tag, which was bound by the antibody of Hopp prior to the time of the instant invention. The reference discloses the antibody to the flag epitope (column 5, lines 55-59) meeting the limitations of the claims. Therefore, the antibody of the reference anticipates instant claims 20-23.

***Claim Rejections - 35 USC § 103***

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hopp et al. in view of the Stratagene catalog (1988, page 39).

This rejection is maintained for reasons of record set forth at pages 9-10 of the previous Office action of 10/15/2003.

Applicants argue that the sequence disclosed in Hopp is not included in SEQ ID NO:3 or encoded by SEQ ID NO:1. Applicants also argue that the Stratagene catalog discloses kits but does not cure the deficiencies in Hopp. However, contrary to Applicants arguments, the claims still recite "comprising" which limitation encompasses an antibody to the flag epitope disclosed in the Hopp reference. Therefore, claim 30 is rendered unpatentable over Hopp et al. in view of the Stratagene catalog.

***Conclusion***

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

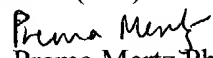
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Prema Mertz Ph.D.  
Primary Examiner  
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March 17, 2004